## REMARKS

Amendments to the Specification

The specification has been amended to update the status of all non provisional parent applications referenced in the first line of the specification. No new matter has been added.

The specification has been further amended at page 33, lines 10-14, to correct a typographical error and to include sequence identifiers. No new matter has been added.

Amendments to the Claims

Claims 80-92 are pending in the application.

Claims 80-84, 86 and 90 have been amended.

Specifically, claims 80-84 and 90 have been amended to specify a nucleic acid "sequence," as suggested by the Examiner. Support for these amendments can be found throughout the specification as filed.

Claim 80 has been further amended to specify that the nucleic acid comprises the nucleotide sequence "as set forth in SEQ ID NO:6 or nucleotide bases 48 through 681 of the nucleotide sequences as set forth in SEQ ID NO:6," as suggested by the Examiner. Support for this amendment can be found throughout the specification as filed.

Claims 80 and 82 have been further amended to provide the full name of the abbreviated protein allergens, as suggested by the Examiner. Support for these amendments can be found throughout the specification as filed.

Claim 86 has been amended to specify an isolated nucleic acid encoding a *Der f* VII protein allergen comprising an amino acid sequence that is at least 95% homologous to the amino acid sequence shown in Fig. 6A and 6B (SEQ ID NO:7), wherein the protein allergen is capable of inducing T cell proliferation specific for *Der f* VII. Support for the amendment of claim 86 can be found throughout the specification, for example, at page 6, lines 11-15, and at page 5, lines 23-25.

Applicant appreciates the Draftsperson's approval of the submitted drawings.

Applicant also appreciates the Examiner's acknowledgement and consideration of the Information Disclosure Statement submitted on April 9, 2002.

The foregoing claim amendments should not be construed as an acquiescence to any of the Examiner's rejections and have been made solely to expedite prosecution. Applicants reserve the right to pursue the claims as originally filed in this or a separate application. No new matter has been added.

***Rejection of Claim 86 Under 35 U.S.C. § 112, First Paragraph***

Claim 86 is rejected for failing "to comply with the written description requirement." In particular, the Examiner is of the opinion that the "written description does not describe polymorphic variants (*i.e.*, allelic variant sequences) of the protein of SEQ ID NO:7 or the single DNA allele comprising a DNA sequence of SEQ ID NO:6."

Claim 86, as amended, is drawn to an isolated nucleic acid encoding a *Der f* VII protein allergen comprising an amino acid sequence that is at least 95% homologous to the amino acid sequence shown in Fig. 6A and 6B (SEQ ID NO:7), wherein the protein allergen has a *Der f* VII activity, *e.g.*, induction of T cell proliferation specific for *Der f* VII. The present specification fully satisfies the written description requirement for claim 86 such that one of ordinary skill in the art would recognize that Applicants had possession of the claimed nucleic acids at the time of filing.

Example 14 of the *Revised Interim Written Description Guidelines Training Materials* provides that a claim directed to variants of a protein having SEQ ID NO:3 "that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→B" with an accompanying specification that discloses a single species falling within the claimed genus, satisfies the requirements of 35 U.S.C. §112, first paragraph for written description. The rational behind the foregoing conclusion, as presented by the *Written Description Guidelines*, is that "[t]he single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which Applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity." The Guidelines also provide that "[t]he procedures for making variants of SEQ ID NO:3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are conventional in the art."

In the present case, claim 86 (as amended) is directed to an isolated nucleic acid molecule as described in Example 14 of the guidelines, *i.e.*, it encodes a *Der f* VII polypeptide comprising an amino acid sequence that is at least 95% identical to the amino acid sequence shown in SEQ ID NO:7, wherein the polypeptide is capable of inducing T cell proliferation specific for *Der f* VII. Thus, claim 86 is analogous to Example 14 of the Revised Written Description Guidelines. Further, Applicants provide in the instant specification assays for identifying all of the at least 95% identical

variants of SEQ ID NO:7 which encode proteins capable T cell stimulation (see, for example, page 12, lines 29 through page 13, line 3; page 13, lines 23-36; page 14, lines 1-5). Thus, as supported by the Interim Guidelines, based on the teachings in Applicant's specification, one of skill in the art would conclude that Applicant was in possession of the claimed invention at the time of filing. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the foregoing rejection.

***Rejection of Claims 82-85 and 90-92 Under 35 U.S.C. § 112, First Paragraph***

Claims 82-85 and 90-92 are rejected for failing "to comply with the written description requirement." In particular, the Examiner is of the opinion that "the specification fails to provide conception by way of written description for the claimed non cross-reactive antigenic peptides and protein allergens capable of stimulating T cells specific for *Der f* VII protein allergen, but not *Der p* VII protein allergen." Applicants respectfully traverse this rejection.

Independent claim 82 (and dependent claims 83, 84, and 90-92) are drawn to an isolated nucleic acid sequence encoding an antigenic peptide of *Der f* VII having the amino acid sequence of SEQ ID NO:7, wherein the peptide is not cross-reactive with *Der p* VII. Independent claim 85 is drawn to an isolated nucleic acid sequence encoding a protein allergen capable of stimulating T cells specific for *Der f* VII protein allergen comprising SEQ ID NO:7, but not *Der p* VII protein allergen.

According to the Written Description Guidelines, the factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention (Federal Register (Friday, January 5, 2001) Vol.66(4) at page 1106, second column). Based on Applicants' teachings (as described in detail below) and the level of skill in the art, including the knowledge of the structural and functional features of *Der p* VII protein allergens (see, for example, Shen *et al.* (1993) Clin and Exp Allergy 23:934-940; Reference CA on the PTOL-1449), the present specification provides sufficient evidence that Applicants were in possession of the claimed invention.

Specifically, with regard to the claimed nucleic acid sequences which encode "non cross-reactive peptides," Applicants clearly teach the existence of cross-reacting family members of *Der p* VII and *Der f* VII (see, for example, page 7, lines 14-17). Such cross-reactive proteins are defined as "proteins related in function and amino acid sequence to *Der p* VII or *Der f* VII, but encoded by

genes at different loci." At page 8, lines 5-8, for example, Applicants also teach screening protocols to detect *Der p* VII or *Der f* VII or allergens that are cross-reactive with *Der p* VII or *Der f* VII. Furthermore, in order to determine precise T cell epitopes, the claimed isolated peptides can be further selected based on various factors including the potential cross-reactivity of the peptide with other dust mite allergens. (see, for example, page 14, lines 13-22).

Accordingly, based on Applicants' teachings concerning the determination of cross-reactive epitopes which utilize the same information and assays as the determination of non cross-reactive epitopes, combined with the level of knowledge and skill in the art regarding house dust mite structure and function, there is sufficient evidence that Applicants were in possession of the claimed non cross-reactive peptides. Therefore, claim 82 and claims dependent on claim 82 are clearly described in the instant specification.

Similarly, the claimed nucleic acid sequences which encode protein allergens capable of stimulating T cells specific for *Der f* VII (SEQ ID NO:7), but not *Der p* VII, are also clearly described in the present application such that one of ordinary skill in the art would recognize that Applicants had possession of the claimed nucleic acids at the time of filing. For example, Applicants describe throughout the specification *Der f* VII protein allergens capable of inducing a T cell response, such as T cell stimulation (see, for example, page 2, line 35 through page 3, line 23). Applicants further provide detailed information on how to measure and determine T cell stimulation through various *in-vitro* assays (see, for example, page 13, line 23 through page 14, line 3). Thus, based at least on these teachings and the foregoing teachings regarding assays which can be used for determining non cross-reactivity, the claimed protein allergens capable of stimulating T cells specific for *Der f* VII protein allergen (SEQ ID NO:7), but not *Der p* VII protein allergens, are clearly described in the instant specification.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 82-85 and 90-92 under 35 U.S.C. §112, first paragraph.

***Rejection of Claims 80-92 Under 35 U.S.C. § 112, Second Paragraph***

Claims 80-92 are rejected for being indefinite. Specifically, the Examiner is of the opinion that claims 80-92 are indefinite for the recitation of the term "an isolated nucleic acid encoding" and for the recitation of the abbreviation "Der f" and "Der p." The Examiner further rejects claim 80 for the recitation of the term "the coding region thereof."

Claims 80-92 have been amended to incorporate the Examiner's suggestions.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 80-92 under 35 U.S.C. § 112, second paragraph.

***Rejection of Claim 86 Under 35 U.S.C. § 102(a)***

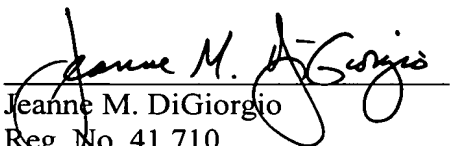
Claim 86 is rejected for being anticipated by Shen *et al.* In particular, the Examiner states that "Shen *et al.* teach the cloning of the *Dermatophagoides pteronyssinus* VII allergen which is 90% homologous to the VII allergen of *Dermatophagoides farinae* of SEQ ID NO:7 as claimed by the Applicants."

Claim 86, as amended, is drawn to an isolated nucleotide sequence that is at least 95% identical to the amino acid sequence shown in SEQ ID NO:7. Shen *et al.* fail to teach the claimed invention. Therefore, claim 86 is novel in view of the cited reference.

**CONCLUSION**

Based on the foregoing, reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,



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